REMARKS

CLAIM REJECTIONS - 35 U.S.C. §112

Claims 1, 4-5, 7, 10-16 and 23 were rejected under U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have amended Claim 1 to overcome the present rejection. Applicants now believe this rejection is moot.

CLAIM REJECTIONS - 35 U.S.C. §102(e)

Claims 1, 4-5, 7, 10-16 and 23 were rejected under 35 U.S.C. §102 (e) as anticipated by Baugh et al. (U.S. Patent 6,656,919). Attached hereto Applicants have submitted a Declaration of Amanda S. Schilling, M.S. Under Rule 131 swearing behind the Baugh et al reference. Applicants now believe this rejection is moot.

CLAIM REJECTIONS - 35 U.S.C. §103

I. Claims 1, 4-5, 7, 10-16 and 23 were rejected under 35 U.S.C. §103(a) as obvious over Baugh et al. (U.S. Patent 6,656,919) in view of Paidhungat et al. (Journal of Bacteriology 2000, Volume 182, Pages 2513-2519), Baker, et al. (U.S. Patent 6,506,803).

Attached hereto Applicants have submitted a Declaration of Amanda S. Schilling, M.S. Under Rule 131 swearing behind the Baugh et al reference. Applicants now believe this rejection is moot.

II. Claims 1, 4-5, 7, 10-16 and 23 were rejected under 35 U.S.C. §103(a) as obvious over Clouston (U.S. Patent 3,617,178) in view of Paidhungat et al. (Journal of Bacteriology 2000, Volume 182, Pages 2513-2519) and Baker, et al. (U.S. Patent 6,506,803), as previously presented. The

Examiner previously stated that:

> Clouston teaches a method to simultaneously germinate *Bacillus*/Clostridial spores present in a solid material and sterilize said material. Alternatively, said material is disinfected by a method, wherein bacterial spores are first germinated and in a subsequent step germinated spores are killed by heat, chemical or radiation treatment. In said simultaneous/ sequential method of germination and sterilization, the spores are germinated via treating the contaminated material with a hydrostatic pressure in range of 100 psi to 20,00 psi accompanied with simultaneous or subsequent heat (up to 80°C) gamma or UV radiation (Column 1, Line 34 to Column 2, Line 19). Said germination is enhanced with addition of an exogenous anion or cation compound (Column 1, Lines 16-19). Thus, intrinsically, Clouston teaches the general principle of first or simultaneous germinating and killing of bacterial spores to sterilize/ decontaminate a liquid/solid contaminated with bacterial spores.
>
> Clouston, while teaching enhancement of germination in presence of cation solutes, does not teach dipicolinic acid and calcium, nor a surfactant or an enzyme in the germinant composition, Paidhungat et al's method comprising a germinant containing <20 mM to 90 mM calcium ions and dipicolinic acid to germinate *Bacillius* spores as well as Baker et al's method and composition to germinate and inactivate bacterial cells and spores by exposing them to an oil-in-water emulsion comprising water, a surfactant, oil, an enzyme and a buffer (Abstract, Lines 1-7; Column 5, Lines 12-15; Column 12, Lines 7-64; Column 18,Lines 18-20; Column 21, Lines 1-32; Column 22, Lines 27-40) has been detailed supra.
>
> Thus, an artisan of ordinary sill, at he time that said invention was made would be motivated to combine the teachings from each one of the cited references to develop a method to decontaminate or sterilize a material contaminated with biological/bacterial spores by either simultaneous or sequential application of a germinate and a germicidal material, because Clouston and Baker et al. teach the general principle of germinating and killing biological spores, Clouston further teaches either simultaneous or sequential killing of said germinated biological spores; Paidhungat et al. teach that a germinant solution to germinate Bacillus spores comprise each of dipicolinic acid and calcium ions in said germinant at a concentration range between 20 to 90 mM and the optimal concentration of each of dipicolinic acid and calcium ions in said germinant is 60 mM, and Baker et al. teach that said germinant solution is comprised of water, surfactant and an enzyme. Thus, Paidhungat et al. remedy the deficiency of concentration of each of dipicolinic acid and calcium ions in Clouston's teachings and Baker et al. remedy the deficiency of an enzyme and a surfactant in germinant composition in Clouston's teachings.
>
> It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify Clouston's method and composition according to the teachings from Paidhungat et al. and Baker et al., because Clouston

> teaches the general principle of first germinating the biological spores and subsequently kill the germinated spores through subjecting said germinated spores to heat, chemical or radiation or alternatively, simultaneously subjecting materials contaminated with biological spores to a pH solution, pressure and heat/radiation or chemical. Paidhungat et al. remedy the deficiency of dipicolinic acid and calcium ions in Clouston's teaching, and Baker et al. remedy the deficiency of enzyme and surfactant in Clouston's method.

Applicants respectfully disagree.

Clouston discloses that "the application of pressure to fluid or solid substances contaminated with bacterial spores causes germination of the spores, thereby reducing their resistance to sterilizing, disinfecting and/or preserving treatments" (see Clouston at col. 1, lns. 17-21). The Examiner's proposition that "intrinsically, Clouston teaches the general principle of first or simultaneous germinating and killing of bacterial spores to sterilize/ decontaminate a liquid/solid contaminated with bacterial spores" relies on the assumption that one skilled in the art would readily disregard the teaching of Clouston for using pressure, and use a methodology devoid of Clouston's disclosure. As Clouston consistently discloses the use of pressure in the decontamination process, any proposition for the non-use of pressure as a methodology to decontaminate spores, purportedly supported by the disclosure of Clouston (that always uses pressure to decontaminate spores), appears erroneous. Neither Baker et al nor Paidhungat et al remedy this deficiency.

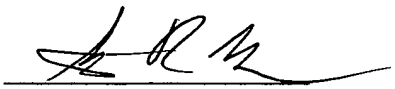
Referring to the Examiner's citation in Baker et al (at Column 21, Lines 1-32), Baker et al teaches that "contamination of farmlands with *B. anthracis* leads to a fatal disease in domestic, agricultural, and wild animals ... animal anthrax infections still represent a significant problem due to the difficulty in decontaminating infected land and farms". The Examiner has shown no practical

procedures (and accordingly no motivation to combine) of how one skilled in the art would use pressure (as taught in Clouston) to solve the significant problem of decontaminating infected land and farms (the problem addressed by Baker et al.). Accordingly, the general teachings of Clouston for using pressure in decontamination has no applicability to the general teachings of Baker et al of how to decontaminate infected land and farms. As such, the Examiner has failed to provide a *prima facie* case to deny patentability of the present invention.

Applicants respectfully request reconsideration of the instant claims, withdrawal of the rejections cited in the Office Action, and allowance of the instant claims.

The Examiner is invited to contact the attorney listed below with any questions or other matters to advance the prosecution of the present application.

Respectfully submitted,



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